

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A., INC.,

Plaintiff,

v.

PAR PHARMACEUTICAL COMPANIES, INC.,
and PAR PHARMACEUTICAL, INC.,

Defendants.

C.A. No. 13-cv-1524-SLR

TAKEDA PHARMACEUTICALS U.S.A., INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS, LLC,

Defendant.

C.A. No. 13-cv-1729-SLR

**AMNEAL PHARMACEUTICALS, LLC'S NOTICE OF JOINDER IN
PAR PHARMACEUTICAL COMPANIES, INC. AND
PAR PHARMACEUTICAL, INC.'S OPPOSITION TO
PLAINTIFF'S MOTION FOR LEAVE TO FILE AMENDED COMPLAINT**

Defendant Amneal Pharmaceuticals, LLC ("Amneal") hereby joins in the arguments contained in Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc.'s (collectively "Par") Opposition to Plaintiff's Motion for Leave to File Amended Complaint and the Declaration in support thereof, C.A. 13-1524-SLR, D.I. 70 and 71 ("Par's Opposition") for the reasons set forth therein, and for the additional reasons set forth in this Notice of Joinder. As set forth in Par's Opposition, Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") seeks to

amend its Complaint to assert against Defendants in both actions twelve new patents that cover the treatment of gout. However, Amneal's products, like Par's, are limited to the treatment of Familial Mediterranean Fever ("FMF") and likewise do not mention gout, will not be approved for treating gout, and cannot be marketed to treat gout.

Amneal submitted an ANDA to the FDA for approval to market a generic Colchicine product initially for the treatment of gout. However, Amneal since changed the sole indication sought in its ANDA from gout to FMF and amended its patent certification in its ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii). *See* attached Declaration of Sherri L. Oslick, Ph.D., Esq. After a hearing on July 23, 2013, this Court stayed the Amneal case relating to gout, 13-cv-493-SLR, D.I. 66, as it did in the Par action, 12-cv-419-SLR, D.I. 98.

The current action against Amneal was filed on October 21, 2013, D.I. 1, alleging infringement of five patents directed to FMF¹. Takeda's first motion for leave to amend its complaint was filed in this action against Amneal on May 13, 2014, D.I. 31. Takeda sought to add back in the twelve gout specific patents under a theory of contributory infringement, despite the section viii carve out provision. That motion was withdrawn on May 30, 2014, D.I. 35, the deadline for Amneal's and Par's oppositions, and refiled, D.I. 36. Amneal has participated in discovery and is operating under the same schedule as Par in these FMF cases.

Amneal joins in the arguments set forth in Par's Opposition and for the additional reasons set forth above, Amneal respectfully requests that the Court deny Plaintiff's Motion for Leave to File Amended Complaint.

¹ Two of the patents relate to the treatment of both FMF and gout.

Dated: June 23, 2014

/s/ Mary B. Matterer

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DECLARATION

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C.A. No. 13-cv-1729-SLR

DECLARATION OF SHERRI L. OSLICK, PH.D., ESQ.

I, Sherri L. Oslick, declare:

1. I am a partner with the law firm of McDonnell Boehnen Hulbert & Berghoff LLP, and I am admitted *pro hac vice* in C.A. No. 13-cv-1729-SLR as counsel of record for Defendant Amneal Pharmaceuticals, LLC (“Amneal”). All matters stated herein are of my own personal knowledge, and if called as a witness, I could and would competently testify thereto.

2. Amneal initially submitted ANDA No. 20-4711 to the FDA with a Paragraph IV certification seeking approval to market a generic colchicine product for the treatment of gout.

3. Amneal thereafter changed the sole indication sought in its ANDA from gout to Familial Mediterranean Fever (“FMF”) and amended its patent certification in its ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(viii).

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 23, 2014

/s/ Sherri L. Oslick
Sherri L. Oslick, Ph.D., Esq.